

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-1015-JLH
	)	
SAREPTA THERAPEUTICS, INC.	)	<b>DEMAND FOR JURY TRIAL</b>
	)	
Defendant.	)	
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	)	
SAREPTA THERAPEUTICS, INC. and THE	)	
UNIVERSITY OF WESTERN AUSTRALIA,	)	
	)	
Defendant/Counter-Plaintiffs,	)	
	)	
v.	)	
	)	
NIPPON SHINYAKU CO., LTD.	)	
and NS PHARMA, INC.,	)	
	)	
Plaintiff/Counter-Defendants.	)	

**FINAL JURY INSTRUCTIONS (PHASE II)**

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**1. GENERAL INSTRUCTIONS**

**1.1 INTRODUCTION**

Members of the jury, now it is time for me to instruct you about the law that you must follow in deciding the second phase of this case.

I have given you instructions at the beginning of each phase and before you began deliberations for Phase One. I will not repeat those instructions now. Instead, I will only explain the contentions of the parties and the law you will apply in this phase. Please listen very carefully to everything I say.

Each of you has been provided a copy of these instructions. You may read along as I deliver them if you prefer. You will have a written copy of these instructions and my instructions from Phase One with you in the jury room for your reference during deliberations. You will also have a verdict form for this phase of the case, which will list the questions that you must answer to decide this case.

## **1.2 BURDENS OF PROOF**

As I explained to you in Phase One, in any legal action, facts must be proven by a required standard of evidence known as the “burden of proof.”

Sarepta and UWA have the burden of proving the amount of any monetary damages by a preponderance of the evidence. That means that Sarepta and UWA have to prove to you, in light of all the evidence, that what they claim is more likely true than not.

## **2. THE PARTIES AND THEIR CONTENTIONS**

As I did at the start of the case, I will first give you a summary of the contentions for this phase of the case. I will then provide you with detailed instructions on what Sarepta and UWA must prove to win on their contentions.

1. Whether Sarepta and UWA have proven by a preponderance of the evidence that they are entitled to lost profits damages as a result of U.S. sales of Nippon Shinyaku and NS Pharma's VILTEPSO® and, if so, the amount of such damages.
2. For any U.S. sales of Nippon Shinyaku and NS Pharma's VILTEPSO® for which Sarepta and UWA have not proven that they are entitled to lost profits damages, the amount of reasonable royalty damages that Sarepta and UWA have proven by a preponderance of the evidence.

### **3. DAMAGES**

#### **3.1 PATENT INFRINGEMENT DAMAGES - GENERALLY**

I will now instruct you about the measure of damages.

The damages you award must be adequate to compensate Sarepta and UWA for infringement by Nippon Shinyaku and NS Pharma. They are not meant to punish Nippon Shinyaku and NS Pharma. Your damages award should put Sarepta and UWA in approximately the same financial position that they would have been in had the infringement not occurred.

While Sarepta and UWA are not required to prove the amount of their damages with mathematical precision, they must prove them with reasonable certainty. You may not award damages that are speculative, damages that are only possible, or damages that are based on guesswork.

There are different types of damages that Sarepta and UWA may be entitled to recover. In this case, Sarepta and UWA seek lost profits and/or a reasonable royalty. Lost profits consist of any actual reduction in business profits the party asserting infringement suffered as a result of the other party's infringement. A reasonable royalty is defined as the money amount the party asserting infringement and the other party would have agreed upon as a fee for use of the invention at the time just prior to when infringement began. But, regardless of the type of damages you may choose to award, you must be careful to ensure that award is no more and no less than the value of the patented invention. Note, however, that the party asserting infringement is entitled to recover no less than a reasonable royalty for each infringing act.

A party asserting infringement may only recover damages for the periods of time for which it held exclusive rights to the patents at issue. If the party asserting infringement possessed only a non-exclusive license to the patents, it cannot collect damages due to infringement during that period.

I will now give more detailed instructions regarding damages.

### **3.2 LOST PROFITS – “BUT FOR” TEST**

I will first instruct you about lost profits damages. To recover lost profits (as opposed to reasonable royalties), Sarepta must show a causal relationship between the infringement and Sarepta’s loss of profit. In other words, Sarepta must show that, but for the infringement, there is a reasonable probability that Sarepta would have earned higher profits. To show this, Sarepta must prove that, if there had been no infringement, it would have made some portion of the sales that NS Pharma made of VILTEPSO®.

It is important to remember that the profits I have been referring to are the profits allegedly lost by Sarepta, not the profits, if any, made by NS Pharma on the allegedly infringing sales.

A party establishes “but for” causation and that it is entitled to an award of its lost profits (as opposed to reasonable royalties) if you find that it has proven each of the following four factors by a preponderance of the evidence:

1. That there was demand for the patented product;
2. That there were no available, acceptable, noninfringing substitute products, or, if there were, the market share of the number of the sales made by the alleged infringer that the party asserting infringement would have made, despite the availability of other acceptable noninfringing substitutes;
3. That the party asserting infringement had the manufacturing and marketing capacity to make any infringing sales actually made by the alleged infringer and for which the party asserting infringement seeks an award of lost profits—in other words, that the party asserting infringement was capable of satisfying the demand;
4. The amount of profit that the party asserting infringement would have made if the alleged infringer had not infringed.



### **3.3 LOST PROFITS – DEMAND FOR PATENTED PRODUCT**

Demand for the patented product can be proven by significant sales of a party asserting infringement's patented product or significant sales of an infringing product containing the patented features.

### **3.4 LOST PROFITS - ACCEPTABLE NON-INFRINGEMENT SUBSTITUTES**

To be an “acceptable, noninfringing substitute,” a product must have the advantages of the patented invention that were important to people who purchased an alleged infringer’s product. If purchasers of an alleged infringer’s product were motivated to buy that product because of features available only from that product and a party asserting infringement’s patented product, then some other, alternative product is not an acceptable substitute, even if it otherwise competed with a party asserting infringement’s and an alleged infringer’s products. On the other hand, if the realities of the marketplace are that competitors other than the party asserting infringement would likely have captured the sales made by the infringer, despite a difference in the products, then the party asserting infringement is not entitled to lost profits on those sales.

### **3.5 LOST PROFITS – CAPACITY**

Sarepta is only entitled to lost profits for sales it could have actually made. In other words, Sarepta must show that it had the manufacturing and marketing capability to actually make the sales it allegedly lost due to infringement by Nippon Shinyaku and NS Pharma. To be awarded lost profits based on additional sales that it claims it would have made, Sarepta must prove that it was more likely than not that it would have had the capacity to manufacture enough products to make those additional sales, as well as the marketing capability to make those additional sales.

### **3.6 LOST PROFITS – AMOUNT OF PROFIT**

Sarepta may calculate its lost profits on lost sales by computing the lost revenue for sales it claims it would have made but for the infringement and subtracting from that figure the amount of additional costs or expenses it would have incurred in making those lost sales, such as cost of goods, sales costs, packaging costs, and shipping costs. Certain fixed costs that do not vary with increases in production or scale, such as taxes, insurance, rent, and administrative overhead, should not be subtracted from Sarepta's lost revenue.

### **3.7 DAMAGES – REASONABLE ROYALTY**

Sarepta and UWA are also seeking damages in the amount of a reasonable royalty.

Sarepta and UWA are entitled to at least a reasonable royalty to compensate them for infringement.

If you find that Sarepta and UWA have not proven their claim for lost profits for sales of Nippon Shinyaku and NS Pharma's VILTEPSO® in the United States, or have proved their claim for lost profits for only a portion of the infringing sales, then you must award those parties a reasonable royalty for all infringing sales for which they have not been awarded lost profits damages.

A royalty is a payment made to a party asserting infringement in exchange for the right to make, use, or sell the claimed invention. A reasonable royalty is the royalty payment that would have resulted from a hypothetical negotiation between the party asserting infringement and the alleged infringer just before the infringement began.

In considering this hypothetical negotiation, you should focus on what the expectations of the party asserting infringement and the alleged infringer would have been if they had entered into an agreement at that time, and if they had acted reasonably in their negotiations. In determining this, you must assume that both parties to the hypothetical negotiation believed the patent was valid and infringed and that both parties were willing to enter into an agreement. The reasonable royalty you determine must be a royalty that would have resulted from the hypothetical negotiation, and not simply a royalty either party would have preferred.

Evidence of things that happened after the infringement first began can be considered in evaluating the reasonable royalty only to the extent that the evidence aids in assessing what royalty would have resulted from a hypothetical negotiation just prior to the first infringement.

### **3.8 REASONABLE ROYALTY – FACTORS**

In determining a reasonable royalty, you should consider all the facts known and available to the parties at the time the infringement began. Some of the kinds of factors that you may consider in making your determination are:

1. Any royalties received by the party asserting infringement for licensing others under their asserted patent, proving or tending to prove an established royalty.
2. The rates paid by the accused infringer to license other patents comparable to the asserted patents.
3. The nature and scope of the license, as exclusive or non-exclusive, or as restricted or non-restricted in terms of its territory or with respect to whom the manufactured product may be sold.
4. The licensor's established policy and marketing program to maintain its right to exclude others from using the patented invention by not licensing others to use the invention, or by granting licenses under special conditions designed to preserve that exclusivity.
5. The commercial relationship between the licensor and the licensee, such as whether or not they are competitors in the same territory in the same line of business.
6. The effect of selling the patented product in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of its non-patented items; and the extent of such collateral sales.
7. The duration of the asserted patent and the term of the license.
8. The established profitability of the patented product; its commercial success; and its current popularity.
9. The utility and advantages of the patented invention over the old modes or devices, if any, that had been used for achieving similar results.

10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.

11. The extent to which the accused infringer has made use of the invention; and any evidence that shows the value of that use.

12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.

13. The portion of the profit that arises from the patented invention itself as opposed to profit arising from unpatented features, business risks, or significant features or improvements added by the accused infringer.

14. The opinion testimony of qualified experts.

15. The amount that a licensor and a licensee (such as the accused infringer) would have agreed upon (at the time the infringement began) if both sides had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a party asserting infringement who was willing to grant a license.

16. Any other economic factor that a normally prudent business person would, under similar circumstances, take into consideration in negotiating the hypothetical license.

No one factor is dispositive, and you can and should consider the evidence that has been presented to you in this case on each of these factors.

### **3.9 DAMAGES – TIMING**

The parties agree that the hypothetical negotiation for purposes of reasonable royalty damages would have occurred in August 2020.



**4. DELIBERATION AND VERDICT**

I have completed my instructions on the law. All the instructions I gave you previously about the rules for deliberations still apply, and you will have a copy of them with you.

I will remind you that, when you start deliberating, do not talk to the jury officer, to me, or to anyone but each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can.

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to the verdict. Your verdict must be unanimous.

I remind you that in your deliberations you are to consider the instructions I have given you as a whole, including the instructions I gave you previously. You should not single out any part of any instruction, including this one, and ignore others. They are all equally important.

Nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourself based on the evidence presented.

You may now retire and continue your deliberations.